

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB236 trade name]*

Cycloserine 250 mg capsules

2. Statement of active substance

Each capsule contains 250 mg cycloserine.

3. List of excipients

Each capsule contains FD&C Yellow #6 (sunset yellow FCF).

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Hard capsule

10 x 10 capsules

5. Method and route of administration

Oral use.

Read the patient information leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep this medicine out of the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Store below 30°C in a dry place and protected from moisture.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

11. Name and address of the supplier

Dong-A ST Co. Ltd.

64, Cheonho-daero, Dongdaemun-gu

Seoul, Republic of Korea

Tel: 82-2-920-8524

Fax: 82-2-924-2662

Email: dasomkim@donga.co.kr

12. WHO Reference Number (Prequalification Programme)

TB236

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Alu-Alu blisters

1. Name of the medicinal product

[TB236 trade name]

Cycloserine 250 mg capsules

2. Name of the supplier

Dong-A ST Co. Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other